IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRAEBURN INC.,

450 Plymouth Road, Suite 400
Plymouth Meeting, PA 19462

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

10903 New Hampshire Avenue,
Silver Spring, MD 20993

NORMAN E. SHARPLESS, in his official capacity as ACTING COMMISSIONER OF FOOD AND DRUGS,

10903 New Hampshire Avenue,
Silver Spring, MD 20993

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

200 Independence Avenue, SW,
Washington, DC 20201

ALEX M. AZAR II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

200 Independence Avenue, SW,
Washington, DC 20201

Defendants.

Civil Action No. 19-982

COMPLAINT

Plaintiff Braeburn Inc. brings this complaint for declaratory and injunctive relief against Defendants the United States Food and Drug Administration ("FDA"), Norman E. Sharpless (in

his official capacity as Acting Commissioner of Food and Drugs), the United States Department of Health and Human Services ("HHS"), and Alex M. Azar II (in his official capacity as Secretary of Health and Human Services). In support thereof, Braeburn states as follows:

INTRODUCTION

1. Opioid addiction, also known as opioid-use disorder or OUD, is one of the greatest public-health crises facing the United States. HHS declared the opioid crisis a "national public health emergency" in October 2017. OUD was responsible for the deaths of nearly 50,000 people in that year alone, and almost 400,000 people since 1999. Braeburn has a new, innovative, and long-lasting treatment for OUD with unique features that can help fight the crisis. FDA has found Braeburn's new drug product safe and effective following the completion of seven clinical studies. But FDA will not approve it until November 30, 2020, because of Defendants' arbitrary and capricious decision to give an unlawfully broad form of marketing exclusivity to another manufacturer's product. In particular, Defendants have granted the other manufacturer's product very broad *exclusivity* despite only providing it a narrow *approval* based on clinical trials conducted in a limited patient population. Braeburn's new treatment has been shown to help patients whom the other manufacturer's product is not approved to treat and in whom it was never studied. Defendants' impermissible interpretation of the exclusivity provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA" or "Act"), 21 U.S.C. § 301 *et seq.*, is thus depriving large numbers of OUD patients of *any* access to potentially life-saving innovations for OUD treatment.

2. One of the most common active chemical ingredients used in drugs for treating OUD is buprenorphine. Buprenorphine was first approved for medical use in 1981, and was approved as an injectable formulation for pain in 1985. FDA first approved a buprenorphine

drug to treat OUD in 2002. Originally, buprenorphine OUD drugs were only studied—and therefore only approved—in oral dosage forms, for daily use. But oral administration of buprenorphine has well-recognized drawbacks. Most notably, it requires an OUD patient to consciously take the appropriate dose—in some cases up to two to four times each day—neither missing a dose nor taking too much. Compliance with that regime is difficult for this sensitive population of patients, which frequently suffers from impaired mental health and diminished decision-making capacity, as well as homelessness or other domestic dislocation. As a result, OUD patients often do not take their medication or do not take the right dose, leading to significant health risks—including drug overdose and death. Sending OUD patients home with a supply of buprenorphine for daily oral administration also carries risks because buprenorphine is itself a controlled substance that can be abused, sold for cash, or otherwise criminally diverted in a manner similar to other prescription and illicit opioids. Moreover, oral buprenorphine presents life-threatening risks to children, with over 2,000 children visiting emergency rooms in 2015 due to accidental buprenorphine exposure.

3. This case concerns Braeburn's new, long-lasting injectable buprenorphine treatment, known as Brixadi. Brixadi is injected in a way that forms a very small "depot" under the skin, which slowly dissolves and releases buprenorphine over an extended period of time. That allows buprenorphine to be administered at much longer intervals than daily treatment, ensuring patient compliance for as long as a month at a time. And because the injection is administered and controlled by a healthcare professional, there is no risk of patient diversion and misuse as compared with oral buprenorphine. In fact, Brixadi's long-lasting formulation does not require a patient to take home a single dose, completely eliminating the significant risks associated with self-administration of oral buprenorphine.

4. Braeburn's new drug application for Brixadi was pending before FDA at the same time as Indivior PLC's application for a different buprenorphine product, called Sublocade. While both Brixadi and Sublocade are depot products, the formulation that each uses to control release of buprenorphine is entirely different. That difference leads to significant differences in when and how the drugs can be used, and—importantly—the patients to whom they can be administered.

5. Both Brixadi and Sublocade were potential candidates for "new clinical study" exclusivity. To incentivize the development of new treatments, the FDCA awards a three-year period of exclusivity when a drug manufacturer conducts "new clinical investigations" that were "essential" to the approval of a new drug that uses an already-known active ingredient. 21 U.S.C. § 355(c)(3)(E)(iii). For instance, that exclusivity can apply when a drug sponsor's "new clinical investigations" show that a known active ingredient can be used to treat a new medical condition or to treat the same condition in a different way. The statute, however, limits the *scope* of that exclusivity to the scope of the innovation supported by the "new clinical investigations": exclusivity extends only to "the conditions of approval" of the new drug product. 21 U.S.C. § 355(c)(3)(E)(iii). Thus, if the "conditions of approval" of a drug are limited to certain indications (*e.g.*, certain diseases or health conditions) or to certain types of patients, then the new clinical study exclusivity for that drug does not bar FDA from approving other products with the same active ingredient for different indications or different types of patients. That scope limitation serves two vital purposes. First, it ensures that the manufacturer is not rewarded with exclusivity broader than the contribution its "new clinical investigation" makes. Second, it avoids the adverse public-health consequences that would result if a drug's exclusivity could

block patients from accessing other drugs that have been approved for *different* conditions or *different* populations.

6. FDA approved Sublocade first, but notably did not approve it to treat all patients with OUD—or even all patients who would benefit from a monthly, physician-administered injection of buprenorphine. Instead, FDA limited Sublocade's approval in important ways. Most notably, Sublocade is indicated for use only in OUD patients who have successfully initiated treatment and dose-adjusted with oral buprenorphine for a minimum of seven days. That induction period is a significant limitation given the patient-compliance and public-health challenges associated with oral buprenorphine. Indeed, in Indivior's own clinical studies of Sublocade (which required all patients to *first* take seven to fourteen days of oral buprenorphine), a quarter of the patients who began the initial treatment with oral buprenorphine were never able to take Sublocade. In short, Sublocade's exclusivity is bounded by a critical "condition of approval": Sublocade is only approved for those patients who can first successfully complete seven days of initiation on oral buprenorphine.

7. Brixadi does not share this or other important "conditions of approval" with Sublocade. That is, based on Braeburn's own clinical study, FDA has found Brixadi safe and effective for treatment of moderate to severe OUD without any requirement that patients undergo a seven-day initiation and dose-adjustment period with take-home oral buprenorphine. Unlike Sublocade, Brixadi's integrated system enables new-to-treat patients to receive an injection on their first visit to the doctor without first navigating seven precarious days on take-home oral buprenorphine, which is subject to the risks of abuse, misuse, and pediatric exposure.

8. Despite these differences, FDA decided that Sublocade's exclusivity bars final approval of Brixadi for monthly administration, in violation of the statutory text and FDA's own

precedent. FDA recognized that Sublocade's "conditions of approval" did not allow it to be used in all OUD patients, because "Sublocade's approved indication is limited to patients who have initiated treatment with [oral buprenorphine] for a minimum of 7 days." Yet it concluded that Sublocade's exclusivity extends *beyond* its approved indication, barring approval of *any* "monthly depot product with buprenorphine as its active moiety that is indicated for treatment of moderate to severe opioid use disorder (OUD)." FDA also confirmed that Sublocade's exclusivity was the sole reason it was not approving Brixadi: it granted Brixadi "tentative approval," which means that FDA has found a drug to be safe and effective for its approved indications, but is withholding final approval solely because another manufacturer's exclusivity blocks it. As a result of Defendants' mistaken exclusivity ruling, the large number of OUD patients who cannot use or otherwise tolerate Sublocade will be barred from access to Brixadi until Sublocade's exclusivity expires on November 30, 2020.

9. FDA's determination of the broad scope of Sublocade's exclusivity, and its corresponding decision to delay Brixadi's final approval based on that exclusivity, violate the FDCA's plain text, as well as FDA precedent interpreting that text. Those decisions are arbitrary, capricious, an abuse of discretion, and contrary to law, and this Court should therefore set them aside pursuant to the Administrative Procedure Act.

PARTIES

10. Plaintiff Braeburn Inc. is a Delaware corporation with a principal place of business in Plymouth Meeting, Pennsylvania.

11. Defendant FDA is an administrative agency of the United States government within HHS. It is the division of HHS specifically charged with administering the FDCA. Its headquarters is located in Silver Spring, Maryland.

12. Defendant Norman E. Sharpless is the Acting Commissioner of Food and Drugs and is responsible for overseeing FDA and administering the FDCA. Acting Commissioner Sharpless is being sued in his official capacity only.

13. Defendant HHS is a cabinet-level department of the United States government. Its headquarters is located in Washington, D.C.

14. Defendant Alex M. Azar II is the Secretary of Health and Human Services. He is ultimately responsible for the implementation of the FDCA and oversight of FDA. Secretary Azar is being sued in his official capacity only.

JURISDICTION AND VENUE

15. This action arises under and asserts violations of the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq.*, and the FDCA. The Court has subject-matter jurisdiction of this action pursuant to 28 U.S.C. §§ 1331, 1346, and 1361.

16. The Court is authorized to grant Plaintiffs' request for declaratory relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

17. Venue in this judicial district is proper under 28 U.S.C. § 1391(b) and (e) and 5 U.S.C. § 703.

STATUTORY AND REGULATORY BACKGROUND

18. Before FDA approves a new drug, the drug sponsor must prove that it is effective and safe for use. *See* 21 U.S.C. § 355(d)(2); *see generally* 21 U.S.C. § 355(a). The Act contemplates three types of drug applications: a full New Drug Application ("NDA") under section 505(b)(1) of the Act, an Abbreviated New Drug Application ("ANDA") under section 505(j) of the Act, and an intermediate form of NDA under section 505(b)(2) of the Act.

19. An NDA under section 505(b)(1) requires that the drug's sponsor provide FDA with its own "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." 21 U.S.C. § 355(b)(1)(A). This process, in other words, requires that the application rest entirely on the drug sponsor's own studies to show the safety and effectiveness of the proposed new drug for its intended use.

20. An ANDA under section 505(j) requires a more limited showing. To obtain ANDA approval, a drug sponsor must only show that the proposed drug is the same in all relevant respects as a previously approved drug, and does not need to conduct new clinical trials (other than studies to show that the new drug is "bioequivalent" to the previously approved drug). 21 U.S.C. § 355(j). Its safety and effectiveness are presumed based on the approval of the previously approved drug. Drugs approved by way of ANDAs are often called "generic" drugs.

21. This case concerns NDAs under section 505(b)(2), which is an intermediate pathway for approval of a new drug. "Like the full NDA, a [section] 505(b)(2) NDA must directly demonstrate that the proposed drug product is safe and effective." *Veloxis Pharm., Inc. v. FDA*, 109 F. Supp. 3d 104, 108 (D.D.C. 2015). However, the section 505(b)(2) NDA sponsor need not conduct all of the clinical studies itself and can rely, wholly or in part, "on clinical studies that were previously submitted to FDA in support of another drug" by a different sponsor. *Id.* at 109 (brackets omitted). Stated otherwise, a section 505(b)(2) application contains full reports of clinical studies demonstrating the safety and effectiveness of the proposed new drug, but differs from a section 505(b)(1) application because it relies, in whole or in part, on safety and/or efficacy data from a previously approved drug, or from published studies. For instance, a drug sponsor can submit an NDA under section 505(b)(2) when it seeks approval for

using a previously approved active ingredient to reach a new patient population. Both Sublocade and Brixadi were submitted under the section 505(b)(2) pathway.

22. The FDCA creates several different kinds of marketing exclusivities. Marketing exclusivities bar FDA from approving closely related drugs through the section 505(b)(2) or ANDA pathways for a specified period of time. *See, e.g.*, 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii). These various marketing exclusivities are carefully calibrated to "strike a balance" between the desire to incentivize research and development of new treatments and the need to ensure that patients have access to the drugs that they need. *See Veloxis*, 109 F. Supp. 3d at 107.

23. This case concerns the three-year new clinical study exclusivity available under section 505(c)(3)(E)(iii) of the Act. That provision states, in relevant part:

> If an application submitted under [§ 505(b)] for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under [§ 505(b)], is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under [§ 505(b)(2)] for the conditions of approval of such drug in the approved [§ 505(b)] application effective before the expiration of three years from the date of the approval of the application under [§ 505(b).]

21 U.S.C. § 355(c)(3)(E)(iii).

24. Thus, a drug is entitled to this new clinical study exclusivity if (1) the drug "includes an active ingredient . . . that has been approved in another [NDA]"; (2) the drug was "approved after September 24, 1984"; and (3) the application for the drug "contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." 21 U.S.C. § 355(c)(3)(E)(iii); *see also* 21 C.F.R. § 314.108(b)(4). The substantive focus of the exclusivity is therefore to encourage

drug applicants to conduct "new clinical investigations" expanding the use of previously approved active ingredients.

25. The *scope* of any new clinical study exclusivity is tied to—and limited by—the drug's "conditions of approval." *See id.*; *see also* 21 C.F.R. § 314.108(b)(4). Specifically, during the three-year period, FDA cannot approve a new section 505(b)(2) NDA "for the conditions of approval of [the] drug" receiving the exclusivity. 21 U.S.C. § 355(c)(3)(E)(iii). This limitation on the scope of exclusivity is vital to ensure that the exclusivity does not deprive some patients of access to *any* safe and effective drug. For instance, if the "conditions of approval" of a drug limit the use of that drug to a particular indication or a particular type of patient, that drug's exclusivity does not bar approval of another drug that is shown to be safe and effective as to *other* indications or *other* patients, even if the drugs share some other relevant conditions of approval, such as the same dosage form or dosing regimen.

26. Although neither the Act nor its implementing regulations expressly define the term "conditions of approval," FDA interprets the phrase to mean the "innovative change that is supported by the new clinical investigations" that entitled the first-approved drug to the new clinical study exclusivity. FDA, General Advice Letter, dated Jan. 15, 2015, at 21 (NDA No. 206406, Envarsus XR), at 21 (attached as Exhibit A) ("Veloxis Letter"). Thus, the scope of exclusivity is "circumscribed by the scope of the 'new clinical investigations' essential to the approval of the change." *Id.* at 23–24. In other words, FDA "interprets the scope of exclusivity to be related to the scope of the underlying new clinical investigations that were essential to the approval. *Exclusivity does not extend beyond the scope of the approval and does not cover aspects of the drug product for which new clinical investigations were not essential*." *Id.* at 22 (emphasis added).

27. When a section 505(b)(2) application is blocked by another drug's exclusivity, the statute bars FDA from "mak[ing] the approval . . . effective" during the exclusivity period. FDA can grant only "tentative approval," which indicates that the application has satisfied all applicable requirements for safety and effectiveness and is blocked only by the rights of another product, such as new clinical study exclusivity. *See* 21 C.F.R. § 314.107(b)(4).

28. FDA applied these principles in evaluating the section 505(b)(2) NDA for the immunosuppressant Envarsus XR ("Envarsus"), which required determining whether final approval of Envarsus was barred by the new clinical study exclusivity for a previously approved drug, Astagraf XL ("Astagraf").

29. In a detailed, fifty-page letter, FDA concluded that Astagraf did *not* bar final approval of Envarsus because the scope of Astagraf's exclusivity was limited based on the type of patients studied in the "new clinical investigations essential to" Astagraf's approval. Specifically, the clinical investigations essential to Astagraf's approval had examined that drug only "for the prophylaxis of organ rejection in *de novo* kidney transplant patients"—*i.e.*, patients who have recently received a transplant and begun taking immunosuppressant drugs. Veloxis Letter, *supra*, at 32; *see also Veloxis*, 109 F. Supp. 3d at 110 (describing "*de novo*" patients). Astagraf's sponsor "did not obtain approval of Astagraf in conversion patients"—*i.e.*, patients who are in the process of converting from one immunosuppressant drug to another." Veloxis Letter, *supra*, at 39 *see also Veloxis*, 109 F. Supp. 3d at 110 (describing "conversion" patients). Astagraf's exclusivity therefore could not "extend beyond" *de novo* patients—notwithstanding the breadth of its label, and could not block FDA from approving Envarsus for conversion patients. *Id.*; *see also id.* at 40 ("[I]t is clear that the new clinical investigations . . . for which Astagraf XL received exclusivity did not also demonstrate the safety and effectiveness of the

Astagraf XL once-daily, ER dosage form for every use (or even just for conversion use), but rather only for *de novo* use in kidney transplant patients.").

30. "In short, the Agency concluded that the conversion use is a different 'condition of approval' from the *de novo* use for which Astagraf XL received exclusivity and that Astagraf XL did not conduct new clinical investigations essential to the approval of Astagraf XL for the conversion use. Therefore, FDA informed [the sponsor of Envarsus XR] of its preliminary determination that Envarsus XR would not be blocked for this condition of approval." Veloxis Letter, *supra*, at 41–42. FDA thus approved Envarsus for use in conversion patients.

FACTUAL AND PROCEDURAL BACKGROUND

The Opioid Crisis and Oral Buprenorphine

31. The nation is in the midst of a growing opioid epidemic. According to the Centers for Disease Control and Prevention, almost 400,000 people died from an opioid-related overdose from 1999 to 2017. Centers for Disease Control & Prevention, *Opioid Overdose: Understanding the Epidemic* (Dec. 19, 2018), https://bit.ly/2jEOHfs. Opioid overdose deaths are projected to result in 700,000 deaths during the period from 2016 to 2025. Q. Chen et al., *Prevention of Prescription Opioid Misuse and Projected Overdose Deaths in the United States*, JAMA Network Open (Feb. 1, 2019), https://bit.ly/2Gr3Krp. In 2017 alone, more than 70,200 people died of a drug overdose, with more than two-thirds of those fatalities—around 68%—attributable to opioid abuse. *Id.* Troublingly, these numbers are on the rise: in 2017, the number of opioid-related deaths was six times higher than the number in 1999. *Id.* Recent data suggest that more than two million Americans currently suffer from opioid-related substance-use disorders. National Inst. on Drug Abuse, *Opioid Overdose Crisis* (Mar. 2018), https://bit.ly/2j6YEE1.

32. The federal government has recognized this escalating crisis, and has made addressing the opioid epidemic in America a top priority. On October 26, 2017, the President declared the opioid crisis a Nationwide Public Health Emergency, "mobilizing his entire Administration to address drug addiction and opioid abuse." The White House, Press Release, *President Donald J. Trump Is Taking Action on Drug Addiction and the Opioid Crisis* (Oct. 26, 2017), https://bit.ly/2VBqPfU. Likewise, on October 5, 2017, officials from HHS and FDA testified before Congress and reiterated the administration's commitment to addressing the crisis. *See* S. Comm. on Health, Education, Labor and Pensions, *The Federal Response to the Opioid Crisis: Written Testimony on Behalf of Witnesses from HHS* (Oct. 5, 2017), https://bit.ly/2RHrPjv. And as part of its five-point strategy to address the opioid epidemic, HHS has pledged to "[i]mprove access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid addiction and to enable individuals to achieve long-term recovery." HHS, *Strategy to Combat Opioid Abuse, Misuse, and Overdose* at 3, https://bit.ly/2R5bhPv.

33. Consistent with that effort, then-FDA Commissioner Gottlieb announced in September 2017 that medication-assisted treatment—*i.e.*, the use of medication in combination with counseling and behavioral therapy—"is one of the major pillars of the federal response to the opioid epidemic in this country." FDA, Press Release, *Statement from FDA Commissioner Scott Gottlieb, M.D., on the Agency's Continued Efforts to Promote the Safe Adoption of Medication-Assisted Treatment for Opioid Addiction* (Sept. 20, 2017), https://bit.ly/2D02WZr. On October 25, 2017, during a House hearing on the federal response to the opioid epidemic, Dr. Gottlieb went even further, calling for the expanded use of medication-assisted treatment and explaining that FDA would issue new guidance to manufacturers to promote the development of

novel therapies, including ones that treat a wider range of symptoms. FDA, Press Release, *Remarks from FDA Commissioner Scott Gottlieb, M.D., as Prepared for Oral Testimony Before the House Committee on Energy and Commerce* (Oct. 25, 2017), https://bit.ly/2FjVxFp. FDA issued its final guidance on February 6, 2019. *See* FDA, *Opioid Use Disorder: Developing Depot Buprenorphine Products for Treatment—Guidance for Industry* (Feb. 2019), https://bit.ly/2F3Dmzo ("2019 OUD Guidance").

34. The most prevalent drug-based treatment for OUD is oral administration of buprenorphine, but oral administration has significant problems and, notably, is not appropriate or adequate for many people with OUD. The success of the oral regime depends on a patient's ability to make a conscious decision to take the prescribed medication—in some cases up to two to four times per day—in the correct amount. Ensuring compliance is often difficult in the context of addiction treatment, especially given complications caused by mental illness, homelessness, and strained financial circumstances. Oral buprenorphine has been repeatedly shown to create risks of drug-overdose deaths, especially in the early days of a patient's treatment. Further, because oral administration requires patients to receive and keep a supply of buprenorphine, which is itself a Schedule III controlled substance, it frequently results in misuse or diversion to the street (especially when patients are homeless or live in group homes). According to FDA, the most frequently reported adverse events observed with oral buprenorphine since its approval have been drug misuse or abuse. Sublocade Label § 6.2 (rev. Nov. 2017), *available at* https://bit.ly/2AIoNln. Take-home oral buprenorphine also creates significant risks of pediatric exposure. From 2007 to 2016, there were nearly three reports to U.S. poison control centers *per day* of buprenorphine exposure in children under the age of six years old. More than twenty percent of these exposures resulted in what were classified as

serious medical outcomes, including instances of major effects and deaths. There is therefore a critical need for a buprenorphine product that avoids the risks from oral buprenorphine.

The Limited Conditions of Approval For Sublocade

35. On May 30, 2017, Indivior submitted a section 505(b)(2) NDA for Sublocade (NDA No. 209819). Sublocade is an extended-release formulation of buprenorphine that uses a system known as the ATRIGEL delivery system to control release of buprenorphine over time. When Sublocade is injected into a patient's abdomen, it forms a solid mass, also known as a depot, that is intended to release buprenorphine over a one-month period. FDA approved the Sublocade NDA on November 30, 2017. *See* FDA, NDA Approval, dated Nov. 30, 2017 (NDA No. 209819, Sublocade), *available at* https://bit.ly/2D3WAqN ("Sublocade Approval Letter").

36. The conditions of Sublocade's approval are limited in important ways. Most notably, Sublocade was only approved for those OUD patients who have first successfully initiated treatment and dose-adjusted with oral (sometimes referred to as "transmucosal") buprenorphine product for at least seven days.

37. This condition on Sublocade's approval is so important that it is included in the "Indications and Usage" section of Sublocade's approved labeling: Sublocade's "Indications and Usage" are expressly limited to OUD "patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of seven days." *See* Sublocade Label, *supra*, § 1. FDA Guidance explicitly recognizes that limitations in the Indications and Usage section limit the scope of FDA approval: "The INDICATIONS AND USAGE section should clearly communicate the scope of the approved indication, including the population to which the determination of safety and effectiveness is applicable." *See* FDA Guidance [Draft], *Indications and Usage Section of Labeling for Human*

Prescription Drug and Biological Products – Content and Format, at 3 (July 2018). Likewise, FDA regulations provide that "[m]ajor limitations of use" must be noted in the Indications and Usage section. 21 C.F.R. § 201.57(a)(6). Indeed, the FDA reaffirmed the link between a drug's indications and its conditions of approval in this very case; its discussion of the exclusivity of the drug Probuphine confirms that limitations on a drug's indication, as stated in its label, are limitations on the drug's "conditions of approval." *See infra*, ¶ 69.

38. This limitation on Sublocade's approval is also repeated elsewhere throughout Sublocade's label. The "Patient Selection" section of the label states that the *only* patients who are "appropriate for SUBLOCADE are adults who have initiated treatment and dose-adjusted on a transmucosal buprenorphine-containing product delivering the equivalent of 8 to 24 mg of buprenorphine daily. *The patient may only be transitioned to SUBLOCADE after a minimum of 7 days*." *Id.* § 2.4 (emphasis added). And Sublocade's "Medication Guide" states that Sublocade is only for patients who "have received treatment with an oral transmucosal (used under the tongue or inside the cheek) buprenorphine-containing medicine for 7 days **and** are taking a dose that controls withdrawal symptoms for at least seven days." *Id.*, Medication Guide, at 1 (emphasis in original).

39. Supporting the importance of this limitation on Sublocade's approval, FDA has recognized that if Sublocade were taken without prior treatment with oral buprenorphine, "there is a risk that precipitated withdrawal, a clinically serious condition, could occur[.]" Sublocade Approval Letter, *supra*, at 4.

40. That Sublocade's "conditions of approval" extend only to patients who have initiated treatment and dose-adjusted with at least seven days of oral buprenorphine follows directly from the new clinical investigations that were essential to Sublocade's approval. FDA's

approval of Sublocade was based primarily on a single, pivotal clinical trial (Study RB-US-13-0001). As part of that study, patients were required to initiate treatment with Suboxone sublingual film for three days, followed by a four- to eleven-day dose-adjustment period. The other new clinical investigation that was essential to Sublocade's approval, Study RB-US-13-0002, likewise required initiation and titration on Suboxone sublingual film. In short, Sublocade was not studied in, or demonstrated to be safe and effective for, patients who had not initiated treatment and dose-adjusted with oral buprenorphine for a minimum of seven days.

41. Sublocade's approval only in patients who have initiated treatment and dose-adjusted with at least seven days of oral buprenorphine is a significant narrowing of the patients who are eligible to access the drug. Patient compliance with oral buprenorphine is typically low—with approximately 58% of patients discontinuing therapy within thirty days—and thus not all OUD patients are able to complete the mandatory seven days of oral buprenorphine needed to access Sublocade. Indeed, in Indivior's Study RB-US-13-0001, many patients (25%) who began treatment with oral buprenorphine did not successfully make it through the study's required seven-to-fourteen days on oral buprenorphine, and were not able to use Sublocade *at all*. Further, requiring that patients take home and use oral buprenorphine for seven days exposes patients to the very health risks that buprenorphine depot products were intended to avoid, including the serious risk of drug overdose and death during the initiation of oral-buprenorphine treatment, as well as the possibility of abuse, misuse, and pediatric exposure with take-home oral buprenorphine. And the seven-day oral-buprenorphine requirement makes Sublocade unusable in many clinical settings, like emergency rooms—forcing clinicians in those settings to prescribe oral, take-home buprenorphine.

42. FDA itself has clearly recognized the safety concerns with the seven-day initiation and dose adjustment with oral buprenorphine, explaining that the availability of a depot injection that does not require preliminary oral buprenorphine "would contribute to safer use of the drug." Sublocade Approval Letter, *supra*, at 4. Avoiding oral administration prior to depot use "increase[es] the likelihood of the patient adherence to treatment from the outset, and reduc[es] the need to provide take-home . . . medication for outpatient use." *Id.* Thus, as part of Indivior's "postmarketing requirements" under section 505(*o*) of the FDCA, FDA has required Indivior to conduct a postmarketing clinical trial exploring whether and how Sublocade can be safely initiated without a prior seven-day titration period on transmucosal buprenorphine. Sublocade Approval Letter, *supra*, at 5 (Study 3308-7). That clinical study is not scheduled to be submitted to FDA until August 2021. *Id.*

43. Sublocade's "conditions of approval" are limited in other crucial respects besides the seven-day period. For example, Sublocade was studied only in a subset of the OUD patient population: patients who were new to OUD treatment. That is, Indivior's "new clinical investigations"—including Study RB-US-13-0001—did *not* study Sublocade in patients who were already stable on an established dose of oral buprenorphine. FDA's approval letter expressly acknowledges this limitation: in the letter, the agency confirms that "SUBLOCADE was studied only in patients new to treatment"—as distinct from "patients who are already clinically stable and abstinent after a period of treatment with transmucosal buprenorphine." Sublocade Approval Letter, *supra*, at 6. Importantly, FDA guidance recognizes that patients new to OUD treatment and those already stable on other OUD treatments are distinct patient populations that should be studied separately. 2019 OUD Guidance, *supra*, at 5. This is consistent with advice FDA provided to Indivior during the development process that different

clinical studies would be required to support approval for "new entrants to treatment vs. established, stable patients." Sublocade Cross-Discipline Team Leader Review and Summary Basis for Approval, p. 14 (Nov. 30, 2017). "Indivior elected to study patients new to treatment, and [FDA] agreed that this claim could be supported" by the studies Indivior ultimately conducted. *Id*.

44. The fact that Sublocade was studied only in new-to-treatment patients is reflected in several limitations on the scope of Sublocade's approval, as seen in its label. In particular, Sublocade's label is completely silent as to *how* a patient who is stable on a known dose of oral buprenorphine would transition to Sublocade. That is in direct contrast to Brixadi's label, which provides a chart clearly explaining how to transition patients from doses of oral buprenorphine to doses of Brixadi. *See infra*, ¶ 55. Indeed, Sublocade's dosing instructions present significant hurdles for patients who are already stable on oral buprenorphine, particularly patients who are stable on a low dose. This is because Sublocade's dosing regimen requires two initial "loading doses" of 300 mg per month, which is much higher than the long-term maintenance dose of 100 mg per month. This dosing limitation is an explicit condition on Sublocade's approval, repeated throughout its label. *E.g.*, Sublocade Label, *supra*, §§ 2.3, 3. As FDA has recognized, this dosing regimen clearly limits Sublocade's utility to "patients new to treatment" (as opposed to "patients who are already clinically stable and abstinent after a period of treatment with transmucosal buprenorphine"). Sublocade Approval Letter, *supra*, at 6.

45. The fact that Sublocade was studied only for use in new-to-treatment patients is further reflected in Indivior's post-marketing commitments: Indivior has committed to conduct an additional study "to evaluate the transition of patients with long term stability on a

transmucosal buprenorphine dose to a monthly dose of SUBLOCADE without the use of a loading dose." *Id.* at 7 (Study 3308-10).

46. In summary, given the express limitations in Sublocade's label, as well as the limits of the "new clinical investigations" that were "essential" to Sublocade's approval, Sublocade's "conditions of approval" under section 505(c)(3)(E)(iii) are circumscribed in important respects—including the fact that Sublocade is only approved for patients who have initiated treatment on, and dose-adjusted with, an oral buprenorphine for a minimum of seven days and the fact that Sublocade was only clinically studied—and only demonstrated to be safe and effective—with respect to new-to-treatment patients. Accordingly, the scope of Sublocade's exclusivity is limited to these "conditions of approval."

The Brixadi NDA

47. Braeburn submitted a section 505(b)(2) NDA for Brixadi (NDA No. 210136) on July 19, 2017—less than two months after Indivior submitted its NDA for Sublocade.

48. Brixadi is a long-lasting buprenorphine product, administered by subcutaneous injection, that uses a novel Fluid Crystal formulation to achieve its extended release. The product is supplied in ready-to-use prefilled syringes and administered by medical professionals. Brixadi has both weekly and monthly formulations to fit the different needs of patients at different phases of their recovery, and to enable direct and immediate conversion of OUD patients on oral buprenorphine to an equivalent dose of injectable buprenorphine. For unstable patients who need more frequent clinic visits, weekly dosing may be advantageous, while monthly dosing intervals may be more suitable for patients who are stable and do not need weekly oversight. Additionally, Brixadi's weekly and monthly formulations are available in several different dosages, thereby allowing medical professionals to administer the lowest

effective dose of buprenorphine, and to potentially provide patients with a path to cessation of medication.

49. Brixadi has been successfully evaluated in seven Phase 1–3 clinical trials, including a pivotal Phase 3 efficacy study and a Phase 3 long-term safety study.

50. Unlike Sublocade, Brixadi does not first require any initial titration period with oral buprenorphine. After taking a single, low oral test dose of buprenorphine to ensure they can tolerate buprenorphine, patients can start using Brixadi the same day without having ever undergone any prior OUD treatment. In Brixadi's clinical studies, fewer than 0.5% of patients did not tolerate buprenorphine. Because of Brixadi's integrated weekly/monthly system, patients can receive their first Brixadi injection during the same office visit in which they take the single test dose of oral buprenorphine. Brixadi therefore requires only one medical appointment to begin injectable treatment and does not require that patients ever take any oral buprenorphine home—or, indeed, that prescriptions ever be issued for oral buprenorphine.

51. Even viewing Brixadi's monthly injection in isolation, there is no requirement for an initial titration period with oral buprenorphine. Instead, Brixadi monthly is intended to be used after patients have initiated treatment with Brixadi weekly, with patients directly transitioning from weekly to monthly dosing based on clinical judgment and using an equivalent dose. In this way, the Brixadi weekly and monthly presentations function as an integrated system designed to avoid the need for an initial titration period with oral buprenorphine.

52. This contrast between Brixadi (which patients may receive after just a single test dose of oral buprenorphine) and Sublocade (which requires seven days of initiation and dose adjustment on take-home oral buprenorphine) is expressly reflected in differences between the two product's labels. As mentioned, Sublocade's Indications and Usage are limited to OUD

"patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of seven days." *See supra*, ¶ 37; *see also supra*, ¶ 38 (describing other sections of Sublocade's label). In contrast, FDA has tentatively approved a label for Brixadi whose Indications and Usage section states that Brixadi "is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine."

53. The ability to forgo a dose adjustment on oral buprenorphine when initiating treatment with Brixadi allows patients, healthcare providers, and the public to avoid the well-acknowledged risks and burdens associated with oral buprenorphine, including the risks of non-compliance, abuse, diversion, and pediatric exposure.

54. Brixadi is also different from Sublocade in that it was studied—and demonstrated to be safe and effective—in both patients who are new to treatment *and* patients who have achieved stability on another form of treatment and seek to transition to a monthly depot product, as evidenced by the Brixadi indication. Brixadi is thus available for immediate use with a flexible dosage offering to address *any* patient profile, and not just limited to a subset of new-to-treatment patients like Sublocade.

55. Because Brixadi was developed for, and studied in, the entire OUD patient population, Brixadi lacks the limitations that make Sublocade inappropriate for patients converting from oral buprenorphine. Brixadi does not require an initial "loading dose"—*i.e.*, a higher, 300 mg dose during the first two months of depot treatment. In addition, Brixadi's label contains express instructions for "Patients Switching from Transmucosal Buprenorphine-containing products to BRIXADI," along with detailed tables matching corresponding doses of

oral buprenorphine to weekly and monthly Brixadi. *See* Sublocade Approval Letter, *supra* (attached Label, § 2.3 & tbls. 1–2).

56. FDA tentatively approved Brixadi on December 21, 2018.

FDA's Exclusivity Determination

57. On October 27, 2017, while both Brixadi and Sublocade were under review by FDA, counsel for Braeburn submitted a letter to FDA raising the issue of exclusivity pursuant to 21 U.S.C. § 505(c)(3)(E)(iii). *See* Letter from Lisa M. Dwyer to Grail Sipes dated Oct. 27, 2017 (attached as Exhibit B). "The fact that two long-acting, injectable buprenorphine products are moving through FDA review process at the same time," the letter explained, "raises questions about how exclusivity will be assigned." *Id.* Ultimately, the letter explained, "if [Sublocade] is approved before [Brixadi], the scope of [Sublocade]'s exclusivity would have legal limits—it would be limited both by the conditions of approval of previously approved buprenorphine products and by the design of [its] 'essential' clinical trials." *Id.* at 4.

58. On December 5, 2017, following FDA's approval of Sublocade, counsel for Braeburn submitted a follow-up letter to the agency regarding the scope of Sublocade's exclusivity. *See* Letter from Scott M. Lassman to Grail Sipes dated Dec. 5, 2017 (attached as Exhibit C). The letter provided detailed legal analysis regarding the potential scope of any new clinical study exclusivity for Sublocade, and the reasons for which that exclusivity would not block approval of Brixadi. In particular, and as relevant here, the letter explained that Brixadi does not share Sublocade's exclusivity-protected "conditions of approval."

59. Counsel for Braeburn supplemented these letters with an additional follow-up letter on July 23, 2018. *See* Letter from Scott M. Lassman to Grail Sipes dated Jul. 23, 2018 (attached as Exhibit D). The letter reiterated and expanded upon the legal reasons for which

Sublocade's exclusivity was circumscribed by the scope of its "conditions of approval." The letter also emphasized the extent to which public health considerations—and, in particular, the growing opioid epidemic—required FDA to ensure that it did not interpret the scope of exclusivity in a way that blocked patients' access to innovative and potentially life-saving drugs.

60. FDA issued its Tentative Approval Letter for Brixadi on December 21, 2018. The letter explained that the agency "ha[d] completed [its] review of this application, as amended" and that the application "is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling." Letter from Sharon Hertz to Susan Franks dated Dec. 21, 2018, at 1 (attached as Exhibit E) ("Tentative Approval Letter"). FDA has thus "determine[d] that [Brixadi] meets the statutory standards for safety and effectiveness." 21 C.F.R. § 314.150(c).

61. At the same time, the letter stated: "Final approval of your application is subject to expiration of a period of patent protection and/or exclusivity. Therefore, final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be granted before the period has expired." Tentative Approval Letter, *supra*, at 1.

62. In a separate, two-page letter, also dated December 21, 2018, FDA provided Braeburn's counsel with limited information about its exclusivity decision in response to counsel's July 2018 letter. *See* Letter from Sharon Hertz to Scott M. Lassman dated Dec. 21, 2018 (attached as Exhibit F).

63. According to that letter, FDA "determined that . . . 3-year exclusivity for Sublocade blocks the approval of Brixadi with regard to its monthly depot product." *Id.* at 1.

64. The letter further stated that "[t]he Agency interprets the scope of 3-year exclusivity under section 505(c)(3)(E)(iii) of the [FDCA] to cover the 'innovative change' from

previously approved drug products containing the same active moiety for which the underlying new clinical investigations were essential to the approval. To determine the scope of exclusivity for Sublocade, we thoroughly reviewed the administrative record for the approval of the Sublocade NDA and the clinical investigations deemed to be essential to its approval in relation to prior approvals of buprenorphine products." *Id.*

65. Based on that analysis, the letter explained, FDA concluded "that the scope of Sublocade's unexpired exclusivity is the use of a monthly depot product with buprenorphine as its active moiety that is indicated for treatment of moderate to severe opioid use disorder (OUD)." *Id.*

66. The letter rejected Braeburn's argument that Sublocade and Brixadi do not share the same "conditions of approval." The totality of FDA's analysis was: "We disagree that Sublocade's exclusivity should be limited to its specific formulation. And, we disagree that the remaining differences between Sublocade and Brixadi are relevant for the purposes of the exclusivity analysis in this instance. As the Agency has stated previously, if a 505(b)(2) NDA shares the exclusivity-protected conditions of approval, the NDA may differ in other ways from the exclusivity-protected product and nonetheless be blocked from approval for the exclusivity-protected approval conditions." *Id.* at 1–2. FDA failed to acknowledge that Sublocade's "exclusivity-protected conditions of approval" were limited by the oral-buprenorphine requirement. FDA equally failed to acknowledge that "exclusivity is circumscribed by the scope of [Sublocade's] new clinical investigations"—which, by FDA's own admissions, is limited to clinical studies isolated to OUD patients who are new to treatment. Nor did it recognize that, as a result of those limitations, Sublocade cannot be used to treat many OUD patients who *could* be treated with Brixadi. As a result, FDA's exclusivity determination extends beyond the scope of

its approval and the patient population in which it was solely studied, and thereby denies those patients access to *any* long-acting injectable buprenorphine therapy.

67. On February 28, 2019, FDA supplemented the analysis contained in its December 21 exclusivity determination. *See* Letter from Sharon Hertz to Mike Derkacz dated Feb. 28, 2019 (attached as Exhibit G).

68. The February 28 letter reiterates FDA's understanding that "the scope of the new clinical investigations essential to approval conducted or sponsored by the applicant determines the 'conditions of approval' for which certain subsequent applications are barred." *Id.* at 13–14. In other words, "FDA's view [is] that 3-year exclusivity covers the innovative change that is supported by the new clinical investigations." *Id.* at 14. "FDA thus interprets the scope of exclusivity to be related both to the scope of the underlying new clinical investigations that were essential to the approval and to the scope of the approval that was supported by those new clinical investigations. Exclusivity does not extend beyond the scope of the approval and does not cover aspects of the drug product for which new clinical investigations were not essential." *Id.*

69. The February 28 letter first considered whether new clinical study exclusivity associated with Probuphine (a previously approved subdermal buprenorphine implant for treatment of OUD) might block approval of Brixadi. FDA's analysis of Probuphine relied on the agency's understanding that limitations on the drug's *indication* as stated in its label are limitations on the drug's "conditions of approval": FDA reasoned that "the indication for Probuphine specifically states that it is not appropriate for new entrants to treatment or for patients who have not achieved and sustained prolonged clinical stability at a low dose of buprenorphine," and that Probuphine's "conditions of approval" therefore included a

requirement that Probuphine patients "have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine containing product." *Id.* at 18. Among other things, FDA concluded that any exclusivity associated with Probuphine did not block approval of Brixadi because Brixadi was "for use in a different patient population than that for which Probuphine is approved," *i.e.*, Brixadi is "not limited to patients who have been stable on a low to moderate dose of buprenorphine for multiple months." *Id.*

70. By contrast, FDA reiterated its view that "the 3-year exclusivity for Sublocade blocks the approval of Brixadi with regard to its monthly depot product." *Id.* at 1. While acknowledging that Sublocade's "approved indication is limited to patients who have initiated treatment with [oral buprenorphine] for a minimum of 7 days," *id.* at 20, the agency concluded that Sublocade's exclusivity was *broader* than that, and barred approval of drugs approved to treat those very patients excluded from Sublocade's indication. In particular, FDA opined that "Sublocade's innovation, for which it received exclusivity, was that the dosing interval provided by the monthly depot product delivered an appropriate amount of buprenorphine over a one-month period to treat moderate to severe OUD." *Id.* at 28. In other words, the agency "consider[s] Sublocade's approval for use of a monthly buprenorphine depot for the treatment of OUD" to constitute the relevant "innovative change" that grants exclusivity, *despite* the explicit limitation on Sublocade's approval reflected in the indication section of its label. *Id.* at 19. The agency thus rejected the conclusion "that the scope of Sublocade's exclusivity is . . . constrained by the use of the specific treatment initiation or dose adjustment schedule" contained in Sublocade's label, including the Indications and Usage section. *Id.* at 20.

71. FDA also disagreed that there are meaningful differences between the patient populations in which Brixadi and Sublocade were studied and demonstrated to be safe and effective. *Id.* at 35.

COUNT I
FDA's Determination Of The Scope Of Sublocade's Exclusivity Violated The Administrative Procedure Act, 5 U.S.C. § 706(2)(A), And The FDCA, 21 U.S.C. § 355(c)(3)(E)(iii)

72. Braeburn repeats and realleges the allegations contained in the preceding paragraphs as if fully set forth herein.

73. The Administrative Procedure Act prohibits Defendants from taking action that is contrary to law or in excess of their statutory authority. 5 U.S.C. § 706(2)(A).

74. Defendants' determination of the scope of Sublocade's new clinical study exclusivity is contrary to the FDCA, and therefore exceeds Defendants' statutory authority. The FDCA limits the scope of Sublocade's exclusivity to its "conditions of approval." 21 U.S.C. § 355(c)(3)(E)(iii). Sublocade's "conditions of approval" were limited in key ways. Most importantly, as FDA's own exclusivity letter recognizes, "Sublocade's approved indication is limited to patients who have initiated treatment with [oral buprenorphine] for a minimum of 7 days." Moreover, as FDA *also* recognized, Sublocade was only studied for use in new-to-treatment patients, *not* patients converting from long-term stable treatment on oral buprenorphine—a limitation reflected in key aspects of Sublocade's label. FDA, however, granted Sublocade exclusivity that extends beyond these conditions of approval and encompasses *any* "monthly depot product with buprenorphine as its active moiety that is indicated for treatment of moderate to severe opioid use disorder (OUD)," even if it is indicated for the very patients *excluded* from Sublocade's indication. Thus, during the exclusivity period, FDA refuses to approve monthly depot products that could be used by the very patients for

whom Sublocade is not an option given its limited "conditions of approval." The FDCA does not permit such an overbroad grant of exclusivity. FDA's grant of exclusivity, and its consequent decision to deny final approval to Brixadi, thus are contrary to law, exceed Defendants' statutory authority, and must be set aside.

75. Plaintiff has exhausted its administrative remedies, or, to the extent that it has not, it is excused from exhausting those remedies because further pursuit of administrative remedies would not further the goals that exhaustion is designed to further.

76. Braeburn has no other adequate remedy at law.

COUNT II
FDA's Determination Of The Scope Of Sublocade's Exclusivity Violated The Administrative Procedure Act, 5 U.S.C. § 706(2)(A)

77. Braeburn repeats and realleges the allegations contained in the preceding paragraphs as if fully set forth herein.

78. The Administrative Procedure Act prohibits Defendants from issuing a final decision that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A).

79. FDA's determination of the scope of Sublocade's exclusivity is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" because it fails to account for crucial limitations on the scope of Sublocade's "conditions of approval," including that Sublocade is only approved for patients who have already initiated treatment and dose-adjusted with oral buprenorphine for seven days.

80. Brixadi's "conditions of approval" do not contain such limitations: patients can receive a Brixadi injection during their first visit to a doctor, after a single test dose to establish buprenorphine tolerance, rather than after a seven-day initiation period on oral buprenorphine.

Patients on weekly Brixadi can transition to monthly Brixadi without ever having to take home oral buprenorphine.

81. Defendants' determination of the scope of Sublocade's exclusivity is also contrary to FDA's longstanding interpretation of section 505(c)(3)(E)(iii). Past FDA decisions establish that exclusivity attaching to one drug does not block approval of a subsequent drug with a different indication even if both drugs share other exclusivity-protected conditions of approval. In the Veloxis Letter, for example, FDA recognized that when the "conditions of approval" of the first-approved drug exclude the use of that drug for particular patients, then that drug's exclusivity does not prevent FDA from approving another drug that has "conditions of approval" that allow it to be used by those patients. In that instance, the second-to-market product (Envarsus) was approved for use in conversion patients because the first-to-market product's (Astagraf) exclusivity was limited to the patients in which it was clinically studied, namely de novo patients. Here, however, FDA has granted Sublocade exclusivity beyond the new-to-treatment OUD population in which Sublocade was clinically studied, thereby barring approval of other drugs for patients even if the "conditions of approval" of those other drugs permit treatment of stable OUD patients. By disregarding the agency's past practice, FDA's overbroad grant of exclusivity to Sublocade is arbitrary and capricious.

82. FDA's decision to delay final approval of Brixadi rested entirely on its determination that Brixadi falls within what FDA determined to be the scope of Sublocade's exclusivity. Had FDA not erred in granting Sublocade an impermissibly broad scope of exclusivity that ignored the two key limitations on its "conditions of approval," it would have no basis for delaying Brixadi's final approval. FDA's decision to delay Brixadi's final approval

was therefore arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, and must be set aside.

83. Plaintiff has exhausted its administrative remedies, or, to the extent that it has not, it is excused from exhausting those remedies because further pursuit of administrative remedies would not further the goals that exhaustion is designed to further.

84. Braeburn has no other adequate remedy at law.

PRAYER FOR RELIEF

Braeburn respectfully prays for the following relief:

1. An order holding unlawful, vacating, and setting aside FDA's decision that Sublocade's exclusivity bars approval of any "monthly depot product with buprenorphine as its active moiety that is indicated for treatment of moderate to severe opioid use disorder (OUD)."

2. A declaration pursuant to 28 U.S.C. § 2201 that Sublocade's exclusivity does not block the immediate, final approval of the NDA for Brixadi; that Defendants' failure to immediately and finally approve the NDA for Brixadi is arbitrary, capricious, and contrary to law; and that the NDA for Brixadi is entitled to immediate, final approval;

3. An injunction ordering FDA to stop applying the invalid marketing exclusivity awarded to Sublocade and to convert the tentative approval of the Brixadi NDA to final approval;

4. An award of reasonable attorneys' fees and costs for pursuing this action pursuant to 28 U.S.C. § 2412; and

5. Such other relief as the Court deems just and proper.

Respectfully submitted,

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